APR - 2 2001

510(k) SUMMARY
BIPOLAR COAGULATION SYSTEM
510(k) NOTIFICATION K01XXXX

K 010112

GENERAL INFORMATION

Manufacturer:

Enable Medical Corporation
6345 Centre Park Drive
West Chester, OH 45069-3863
(513) 755-7600
(513)755-7676
Est. Reg. No. 1530251

Contact Person:

Mark L. Friedman, Ph.D.
Vice President of Quality Assurance & Regulatory Affairs
Enable Medical Corporation

Date Prepared:

[to be added after 510(k) process]

DEVICE DESCRIPTION

Classification:

Class II

Trade Name:

Bipolar Coagulation System

Generic/Common Name:

Electrosurgical cutting and coagulation de. ice and Accessories 21CFR878.4400

PREDICATED DEVICES

Bipolar Coagulator

Ethicon Non-Stick Bipolar Forceps	K973384
Link Technology's Non-Stick Bipolar Forceps	K992931
Hysterx, Inc Micrograsp Bipolar Coagulator, Models 9004	K000911
ITI Medical Technologies, Inc Midas Touch Bipolar Forceps	K982705

Electrosurgical Generator

Rita Model 1500 Electrosurgical RF Generator	K993944
Somnus Medical Model S1 Electrosurgical Generator	K000501
Somnus Medical Model S2 Electrosurgical Generator	K001438
Richard Wolf Bipolar Generator Model 2351-2352	K945914

Bipolar Coagulation System

Boston Scientific Tissue Coagulation System	K981981

INTENDED USE

The Bipolar Coagulation System's intended use is to coagulate soft tissues during general and open surgical procedures.

PRODUCT DESCRIPTION

The Bipolar Coagulation System consists of two components: Bipolar Coagulator and an Electrosurgical Generator.

The Bipolar Coagulator is substantially equivalent to the predicate Bipolar Forceps in that each consists of a handle connected to a pair of grasping jaws with electrodes on each jaw arm. All the devices utilize the same bipolar electrosurgical technology, i.e., radio frequency (RF) energy, to coagulate the tissue by heating. The Bipolar Coagulator contains a negative and positive electrode on opposite jaw arms. The function of the Bipolar Coagulator and predicate devices is the same; current flows from a negatively charged pole through the tissue to a positively charged pole. The Bipolar Coagulator is provided as a sterile single patient use device and is provided in a variety of shapes and sizes. The Bipolar Coagulator is constructed with standard biocompatible materials used for medical devices involved in tissue contact.

The Bipolar Coagulator is designed to grasp tissue between the electrodes. When energy is applied, the tissue touching the electrodes is coagulated. The field of coagulation extends up to 2mm from the electrode. Area of coagulated tissue will be up to 4mm in width or up to 60mm in length. Fully coagulated tissue can be achieved for tissue thickness less than 10mm.

The Electrosurgical Generator is set to deliver 750 mA of current. As tissue coagulation proceeds the impedance increases. The voltage is set to not exceed 75 Volts. When a voltage of 75 Volts is reached, the impedance increases and current flow decreases with voltage maintained at 75 Volts. Impedance of 400 ohms typically indicates fully coagulated tissue. The unit will display the impedance, current, voltage, and power on the front of the generator. The unit will also monitor the temperature of the coagulated tissue and has a range up to 125 degrees Celsius. The surgeon may also use this temperature reading as a point of reference to determine extent of tissue coagulation. The entire Bipolar Coagulation System meets the following performance industrial/international standards.

ANSI/AAMI HF18	Electrosurgical Devices
ANSI C101-1992	American National Standard for Leakage Current for Appliances
AAMI ESI – 1993	Safe current limits for electromedical apparatus
ISO 10993/EN 30993	Biological Evaluation of Medical Devices
ISO 11607	Packaging for Terminally Sterilized Medical Devices
ISO 11137	Sterilization of Health Care Products, Sterilization of Gamma Irradiation

IEC/EN 60601-1	Medical Electrical Equipment – Part 1: General Requirements for Safety
IEC/EN 60601-1-1	Medical Electrical Equipment: Collateral standard: Safety requirements for medical device systems
IEC/EN 60601-2	Medical Electrical Equipment – Part 1: General Requirements for safety 2. Collateral standard: electromagnetic compatibility – requirements and tests.
IEC/EN 60601-2-2	Medical Electrical Equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment.
EN 46001	Application of EN ISO 9001 to the manufacture of medical devices
UL 2601-1	Standard for Safety; Medical Electrical Equipment
UL 544	Standard for Safety Medical & Dental Equipment
UL 498	Standard for Safety; Attachment Plugs and Receptacles

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mark L. Friedman, Ph.D.
Vice President of Quality Assurance
and Regulatory Affairs
Enable Medical Corporation
6345 Centre Park Drive
West Chester, Ohio 45069-3863

Re: K010112
Trade Name: Bipolar Coagulation System
Regulatory Class: II
Product Code: GEI
Dated: January 10, 2001
Received: January 12, 2001

Dear Dr. Friedman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010112

Device Name: Bipolar Coagulation System

Indications For Use:

The Bipolar Coagulation System is indicated to coagulate soft tissue during general and open surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010112

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)